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10/606,409

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Medtronic

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EXAMINER

BECCIA, CHRISTOPHER J

ART UNIT

PAPER NUMBER

3775

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|---------------------------------------|--|--|
| Office Action Summary | Application No. 10/606,409 | Applicant(s) SHAOLIAN ET AL. | |
| | Examiner CHRISTOPHER BECCIA | Art Unit 3775 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 2 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant argues that “Palestrant does not teach a plurality of elastically deformable blades that can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed.”
2. Examiner argues that the deformed and undeformed positions of Palestrant are no different than those in the Applicant’s invention. As seen in the Applicant’s invention in Figs 11-14 and described in [0109], Fig. 11 shows the enucleation device with the blades in the insertion position. The blades are retracted in the same manner as the insertion position of Palestrant, as seen in Palestrant Fig. 1. Next, Fig. 12 of the Applicant’s invention shows the expanded cutting position, corresponding to Fig. 2 of Palestrant. [0114] describes the entry of the device into the channel, with the blades in what is described as the “deformed” position. Once in the channel, the blades “undeform.” Examiner believes that these “deformed” and “undeformed” positions are anticipated by Figs. 1 and 2 of Palestrant. The mechanisms of insertion in a “retracted” position and cutting in an “expanded” position are no different. Further, the method claimed in Claim 4 of the Applicant’s invention indicates “actuating the device, thereby effecting cutting of the material.” The indication of the actuation of the device to enable cutting further strengthens the parallels between the Applicant’s invention, and that of Palestrant.
3. Applicant argues that “Palestrant discloses cutting members that cannot cut material when not deformed, but instead can cut material only when they are bowed

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(i.e., deformed). Palestrant's cutting members also do not access a space when deformed, but instead access a space while in their normal (straight) position."

4. Examiner argues the point stressed above that the mechanisms of insertion in a "retracted" position and cutting in an "expanded" position are no different. Col. 7, Lines 65-69 and Col. 8, Lines 1-8 of Palestrant described the position in Figs. 1 and 3 as a "collapsed position." This collapsed position corresponds directly to the "deformed position" as seen in Applicant's Fig. 11, and Palestrant's Fig. 2 the "undeformed" or expanded position corresponds directly to Applicant's Fig. 12.

5. Applicant argues that "The shaft of Ratcliff is held stable in a handle and is not flexible." Applicant's arguments with respect to claims 1, 4-6, 11, 14, 18, and 19 have been considered but are moot in view of the new ground(s) of rejection. Examiner also states that *Ratliff* teaches a stabilized shaft, but by no means does that prevent the capability of it being flexible.

6. Applicant argues that "Groshong fails to teach a plurality of blades that can cut material when not deformed, as recited in the present claims. Rather, Groshong's "blades" can cut material only when bowed (i.e., deformed). (Col. 7, line 50.)

Groshong's "blades" also do not access a space when deformed, but instead access a space while in a normal (straight) position. (Col. 7, lines 50 - 55.)" And "In addition, Groshong teaches only a single blade 52." Applicant's arguments with respect to claims 1, 4, 8, 11, and 13 have been considered but are moot in view of the new ground(s) of rejection.

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7. Applicant argues that "Middleton discloses a rigid shaft, and discloses a cutting element that can cut material in a space when the blade is deformed, after accessing the space when the cutting element is not deformed -- directly opposite the elements recited in the present claims." Applicant's arguments with respect to claims 1, 4, 9, 10, 11, and 15-17 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1 and 3** are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,030,201 to *Palestrant*.

As to **Claims 1 and 3**, *Palestrant* teaches a device capable of enucleation comprising: a proximal end; a distal end comprising a cutting cap comprising a plurality of elastically deformable blades (36, 38, 40, etc.); and a flexible shaft (26) between the proximal end and the cutting cap; where the plurality of elastically deformable blades (36, etc.) can cut material in a space when the blades are not deformed, after accessing the space through a passage while the blades are deformed; and where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades

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are cutting the material; wherein an axial guidewire lumen (surrounding wire 32) extends between the proximal end and the distal end.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 4-6, 11, 14, 18, and 19** are rejected under 35 U.S.C. 102(b) as being unpatentable by U.S. Patent No. 5,709,697 to *Ratcliff et al.* in view of U.S. Patent No. 5,030,201 to *Palestrant*.

As to **Claims 4-6, 11, 14, 18, and 19**, *Ratcliff et al.* teach a method of cutting material in a space, comprising: providing device having a proximal end, a distal end comprising a cutting cap comprising a plurality of deformable blades (160) formed of shape memory alloy (line 45 of column 4); and a shaft (112) between the proximal end and the cutting cap, where the plurality of elastically deformable blades (160) can cut material in a space when the blades (160) are not deformed, after accessing the space through a passage while the blades are deformed; and where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades (160) while the blades (160) are cutting the material; accessing the space with the device (line 36 of column 5); actuating the device, thereby, effecting cutting of the material (line 45

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of column 5 through line 17 of column 6); deforming the blades before actuation the device, and accessing the space through a passage while the blades are deformed; where the passage has a smaller cross-sectional area than the lateral cross-sectional area of the undeformed blades while the blades are cutting the material (lines 46-65 of column 5); retracting the cutting device after cutting material (lines 23-29 of column 6).

Concerning the limitations of claim 6 requiring the passage be curved, it is noted that *Ratcliff et al.* indicate the device, in use, can be inserted through a trochar cannula (line 38 of column 5). Trochar cannulas are known to have round (curved) cross-sections.

Ratliff teaches the claimed invention except for wherein the shaft is flexible.

Palestrant teaches the enucleation device of Claim 1 with a flexible shaft (26) in order to be able to be slidably inserted into a cavity (Col. 7, Lines 22-36).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shaft of *Ratliff* with the flexible modifications of *Palestrant*, in order to allow the shaft to be slidably inserted into a cavity (Col. 7, Lines 22-36).

2. **Claims 7 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,709,697 to *Ratcliff et al.* in view of U.S. Patent No. 5,030,201 to *Palestrant* as applied to claims 4 and 11 above, and further in view of the following.

As to **Claims 7 and 12**, *Ratcliff et al.* teach all of the limitations of the present invention except advancing the device in the space to cut additional material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of *Ratcliff et al.* a second time (advancing the cutting device in the space to cut additional material), since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art: *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

4. **Claims 8 and 13** are rejected under 35 U.S.C. 102(b) as being unpatentable by U.S. Patent No. 5,709,697 to *Ratcliff et al.* in view of U.S. Patent No. 5,030,201 to *Palestrant*. In further view of U.S. Patent No. 5,178,625 to *Groshong*.

As to **Claims 8 and 13**, *Ratcliff et al.* in view of *Palestrant* teach the claimed invention except for wherein advancing the cutting device through the passage comprises advancing the cutting device over a guide wire (lines 15-62 of column 11).

Groshong teaches an enucleation device wherein advancing the cutting device through the passage comprises advancing the cutting device over a guide wire (lines 15-62 of column 11).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the shaft of *Ratliff* with the flexible modifications of

Palestrant, and guide wire of *Groshong* in order to provide additional support and ease for introducing the enucleation device into the cavity.

3. **Claims 9, 10 and 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,709,697 to *Ratcliff et al.* in view of U.S. Patent No. 5,030,201 to *Palestrant* in further view of U.S. Patent No. 5,178,625 to *Groshong* and further in view of U.S. Patent No. 5,972,015 to *Scribner et al.*

As to **Claims 9, 10 and 15-17**, *Palestrant et al.* teach the claimed invention except for wherein the material cut is intervertebral disk and vertebral endplate material; and advancing the device through a transpedicular access passage in a vertebra.

Scribner et al. teach treating diseased vertebrae via a transpedicular approach (Figs. 5, 6, 7 & 8) and indicated in a transpedicular approach is typical (lines 47-60 of column 6), which would allow for intervertebral disk and endplate material to be cut.

It would have been obvious to one of ordinary skill in the art at the time of the present invention to use a transpedicular approach as taught by *Scribner et al.* with the tissue removal method of *Palestrant et al.* as one of a finite number of known and predictable solutions for accessing the intervertebral space.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BECCIA whose telephone number is (571)270-7391. The examiner can normally be reached on M-F 7:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BECCIA/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775